MEMORANDUM OF UNDERSTANDING

between

The National Institute of Standards and Technology

and

The National Cooperation for Laboratory Accreditation

July 13, 2000

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Preamble

The National Institute of Standards and Technology (NIST) of the U.S. Department of Commerce and the National Cooperation for Laboratory Accreditation (NACLA) hereby state their commitment to develop and maintain a system in the U.S. that will (a) recognize competent laboratory accreditation bodies to accredit testing and calibration laboratories when the services of such laboratories are required to demonstrate compliance with procurement, regulatory, and other requirements of government at all levels - Federal, State, and local - and to meet the needs of the private sector, (b) encourage the use by government and the private sector of such accreditation bodies, and (c) recognize competent laboratory accreditation bodies to carry out specific activities in support of NIST in its role as a designating authority under government-to-govemment mutual recognition agreements and arrangements.

1. Purpose

1.1. NIST and NACLA agree on the need for a coordinated national approach to the accreditation of testing and calibration laboratories to eliminate unnecessary duplication and complexity in the development and promulgation of laboratory accreditation requirements and measures by government at all levels and by the private sector.

1.2. NIST and NACLA agree on the need for a coordinated national approach to the accreditation of testing and calibration laboratories to support government-to- government trade agreements.

1.3. NIST and NACLA recognize the need for improved communication between and within the private and public sectors on laboratory accreditation requirements and practices and the need for affected U.S. government agencies at all levels to contribute to the development, -implementation, and use of a system that reduces redundancy and complexity (to the maximum extent possible) while still meeting procurement, regulatory, and other requirements.

1.4. NIST and NACLA agree on the need to monitor reductions in duplicative audits and requirements, as well as savings in resources and improvements. in efficiency, that result from the NACLA recognition process and to share their respective findings on an annual basis.

2. NIST Responsibilities

2.1. In accordance with its responsibilities under the National Technology Transfer and Advancement Act of 1995 (Public Law 104-113), NIST will continue to coordinate laboratory accreditation activities of Federal, State, and local entities with those of the private sector and will strive to eliminate unnecessary duplication and complexity in the development and promulgation of such requirements and measures. NIST will encourage government agencies at all 'levels to accept the use of laboratory accreditation bodies recognized by NACLA when testing and calibration services are required to demonstrate compliance with procurement, regulatory, and other requirements of the U.S. Federal Government and of State and local governments. NIST will work with other U.S. Federal agencies to ensure that agency-unique accreditation requirements are understood by NACLA and incorporated to the extent possible in targeted evaluations by NACLA to minimize duplication and inefficiency in laboratory accreditation activities. NIST intends to use the provisions of this Memorandum of Understanding (MOU) to ensure that NACLA recognition fulfills the needs of agencies in this area, through the verification process referred to in Article 3.1 of this MOU.

2.2. Under the provisions of Section 286.2(b)(3) of Title 15 of the U.S. Code of Federal Regulations, NIST has determined after public consultation that recognition of laboratory accreditation bodies by NACLA provides a suitable alternative to direct NIST recognition under National Voluntary Conformity Assessment System Evaluation (NVCASE) procedures, and thus NIST intends to use the provisions of this MOU to ensure that NACLA recognition fulfills requirements of the international.agreements and arrangements set forth in Articles 2.3 and 2.4 below. Appendix A[1] of this MOU lists specific technical requirements for each of these agreements and arrangements.

2.3. In furtherance of NIST's role in carrying out its responsibilities as a designating authority, NIST will accept NACLA recognition of the competence of laboratory accreditation bodies located in the United States to accredit testing laboratories to meet the technical requirements for their acceptance by European Community Member State governments under the Electromagnetic Compatibility (EMC) Annex of the Agreement on Mutual Recognition between the United States of America and the European Community. Individual laboratories located in the United States and accredited by a NACLA-recognized laboratory accreditation body accepted by NIST may apply to NIST for designation as Conformity Assessment Bodies (CABS) under the Agreement, subject to the terms and conditions of the Agreement.

2.4. Section 5.3 of the Inter-American (CITEL) Mutual Recognition Agreement for Conformity Assessment of Telecommunications Equipment and Section 5.3 of the Asia-Pacific Economic Cooperation Mutual Recognition Arrangement for Conformity

'Appendices A, B and C are integral parts of this Memorandum of Understanding.

Assessment of Telecommunications Equipment empower NIST, as a designating authority, to appoint accreditation bodies located in the United States to accredit laboratories that may then be designated by NIST as Conformity Assessment Bodies (CABS) for specified scopes of testing activity. Whenever a laboratory accreditation body located in the United States obtains recognition by NACLA in a technical area that permits the laboratory accreditation body to accredit laboratories to conduct tests to assess conformance to specific legal, regulatory, and administrative requirements covered under either the CITEL Agreement or the APEC Arrangement, and upon application to NIST documenting NACLA recognition, NIST will appoint that body to be an accreditation body under the relevant framework. NIST shall promptly withdraw the appointment should the laboratory accreditation body cease to be recognized by NACLA in the relevant technical area. Individual laboratories located in the United States and accredited by a laboratory accreditation body that has been appointed by NIST under this section may apply to NIST for designation as CABs under the CITEL Agreement and/or the APEC Arrangement, subject to the terms and conditions of each.

2.5. NIST will encourage laboratory accreditation bodies, including those bodies whose services are used by Federal, State, and local government for procurement, regulatory, trade, and other support purposes, to seek NACLA recognition.

2.6. NIST will work with Federal, State, and local agencies to monitor reductions in duplicative audits and requirements, as well as savings in resources and improvements in efficiency, that result from the NACLA recognition process. NIST will share these findings with NACLA on at least an annual basis.

2.7. NIST representatives will inform NACLA of developments and changes in Federal, State, and local government policy with regard to laboratory accreditation, in a reasonable timeframe whenever NIST becomes aware of such new developments and changes.

2.8. NIST representatives will participate as appropriate in the activities of NACLA.

3. NACLA Responsibilities

3.1. NACLA has developed and implemented a program for recognizing competent laboratory accreditation bodies through the use of accepted international standards and guides and operates in compliance with relevant national and international standards and guides. NACLA will continue to conduct this program and will submit to periodic third party assessments as deemed necessary by the Director of NIST Technology Services to verify that NACLA recognition of laboratory accreditation bodies is carried out in conformance with the criteria in Appendix B of this MOU. NIST will verify NACLA conformance using the process outlined in Appendix C. NACLA will maintain integrity and impartiality in the way it applies

relevant standards and guides and judges conformity to them, and will not show undue preference for one competent laboratory accreditation body versus another. In addition, NACLA will, in consultation with and with the approval of the Director of NIST Technology Services, establish impartial and objective procedures and policies for the resolution of appeals made against NACLA recognition decisions. These procedures may include the use of Alternative Dispute Resolution as appropriate.

3.2. NACLA will encourage the private sector to specify the use of laboratory accreditation bodies recognized by NACLA when testing and calibration services are required to demonstrate compliance with procurement, regulatory, trade, and other requirements. NACLA will also so encourage the public sector.

3.3. NACLA will encourage laboratory accreditation bodies, including those whose services are used by the private sector to demonstrate compliance with procurement, regulatory, trade, and other requirements, to seek NACLA recognition.

3.4. Building on the existing NACLA program for recognizing competent laboratory accreditation bodies through the use of accepted international standards and guides, NACLA will evaluate the competence of laboratory accreditation bodies to accredit testing and calibration laboratories to meet the legal, regulatory, and administrative requirements necessary for their acceptance by foreign governments under the provisions of those agreements and arrangements specified in Articles 2.3 and 2.4 of this MOU.

3.5. NACLA will work with the private sector to monitor reductions in duplicative audits and requirements, as well as savings in resources and improvements in efficiency, that result from the NACLA recognition process. NACLA will share these findings with NIST on at least an annual basis.

4. Other Understandings, Agreements, and Arrangements

4.1. Nothing in this MOU precludes either NIST or NACLA from entering into other MOUS, agreements, or arrangements related to laboratory accreditation.

5. Reviews

5.1. Officials of NIST and NACLA will meet at least annually to review this MOU, cooperative efforts of the previous year, and plans for the coming year.

6. Term

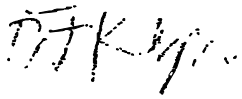
6.1. This MOU will remain in effect for a period of 5 (five) years from the date of the last signature below. It may be extended for additional periods by mutual

agreement of the two parties. It may be amended by agreement of the two parties or terminated with 30 (thirty) days written notice by either party.

Signed on behalf of NACLA on this 13"' day of July 2000:

Donald N. Heirman President NACLA

Signed on behalf of NIST on this 13"' day of July 2000:



Richard F. Kayser
Director, Technology Services NIST
Technology Administration U.S. Department of Commerce

APPENDIX A

SPECIFIC TECHNICAL REQUIREMENTS FOR INTERNATIONAL AGREEMENTS AND ARRANGEMENTS

1. Agreement on Mutual Recognition between the United States of America and tile European Community (U.S.-EU MRA) - EMC (Electromagnetic Compatibility) Sectoral Annex

Introduction

In order to ensure conformance of a product with Council Directive 89/336/EEC (the EMC Directive), Article 10.2, when a manufacturer has not applied any, or has applied only part, of the standard(s) referred to in Article 7(l), the manufacturer must utilize the services of a Competent Body. In such a situation the Competent Body will be required to develop a Technical Construction File (TCF) that describes the apparatus, sets out the procedures used to ensure conformity of the apparatus with the protection requirements referred to in Article 4 and incl ude a technical report or certificate obtained from the Competent Body. Under the U.S.-EU MRA, EMC Annex, a U.S. body may be designated as a Conformity Assessment Body (CAB) and will thus operate as the equivalent of a Competent Body. (EMC CAB Type 1)

U.S. CAB Requirements

EMC CAB Type 1: This type of CAB shall be accredited by an accreditor that has been recognized by NIST to be in conformance with ISO/IEC Guide 58. The CAB must operate in accordance with ISO/IEC International Standard 17025: *General Requirements for the Competence of Testing and Calibration Laboratories*, or in the short term prior to complete implementation of ISO/IEC International Standard 17025, with ISO/IEC Guide *25: General Requirements for the Competence of Calibration and Testing Laboratories.* A CAB may use any appropriate technical standard that it, or the manufacturer, chooses to examine the product. The scope of accreditation must include test methods relevant to the claimed scope of competence of the CAB.

The CAB must also demonstrate its capability to evaluate data relevant to assess the conformity of products covered by the EMC directive, regardless of whether the manufacturer has applied relevant harmonized standards. The body must be able to demonstrate knowledge of the EMC Directive and, in particular, knowledge of how to develop or evaluate a TCF. NIST will continue to be responsible for ensuring the technical competence of CABs for these additional activities, which are not covered by accreditation to ISO/IEC Guide 25 or ISO/IEC IS 17025.

CAB Restrictions

The United States can only designate a CAB located in the United States. During the transition phase of the MRA, which extends through December 3, 2000 and provides for mutual acceptance of test data and reports by the MRA Parties, a U.S. CAB must send all TCF evaluation reports and dossiers for type examination certificates to an EU competent body for approval. This restriction will not apply after the MRA enters its operational phase, at which time listed U.S. CABs can carry out all of the activities of an EU Competent Body.

Subcontracting

A CAB may subcontract some evaluation activities to another body. However, the CAB will be fully responsible for all subcontracted work, e.g., test data, review of dossier results, etc.

2. Asia-Pacific Economic Cooperation (APEC) Mutual Recognition Arrangement for Conformity Assessment of Telecommunications Equipment, Phase 1

Introduction

Under Phase I procedures of the APEC MRA, partner economy regulatory bodies agree to mutually accept test data supplied with an application for equipment approval that supports the claim that equipment complies with the regulations. At the current time participating APEC partner economies are Australia, Canada, Japan, Korea, Singapore, Taiwan, the United States and Hong Kong.

The specific technical requirements for each economy are different and varied. In some cases a partner economy will accept test data produced using accepted international standards/methods, other countries' standards/methods, or other standards/methods that are appropriate for the specific application. In some cases the partner requires that only its own standards/methods be used.

U.S. CAB Requirements

A U.S. CAB must be accredited to ISO/IEC International Standard 17025: *General Requirements for the Competence of Testing and Calibration Laboratories,* or in the short term prior to complete implementation. of ISO/IEC International Standard 17025, to ISO/IEC Guide 25: *General Requirements for the Competence of Calibration and Testing Laboratories* to perform the required testing, by a NIST-recognized accreditor that complies to ISO/IEC Guide 58. The specific technical requirements can be found at the individual websites as indicated below. In addition to being capable of carrying out specific test methods, a CAB must understand each individual partner's regulations and the approval process for the equipment that they desire to be designated to test.

Website List

NIST Conformity Assessment: http://ts.nist.gov/mra

APEC MRA:	http://apii.or.kr/telwg click: MRA Task Group, Task Group input documents
Australia:	http://www.dcita.gov.au
Canada:	http://strategis.ic.gc.ca
Hong Kong:	http://www.ofta.gov.hk
Japan:	http://mpt.go.jp
Korea:	http://www.mic.gov.kr (Korean only)
Singapore:	http://www.ias.gov.sg
Taiwan:	EMC: http://www.bsmi.gov.tw
	Telecom: http://www.dgt.gov.tw

CAB Restrictions

The United States can only designate a CAB located in the United States.

Subcontracting

A CAB may subcontract some evaluation activities to another body. However, the CAB will be fully responsible for all subcontracted work, e.g., test data, review of dossier results, etc.

3. Asia-Pacific Economic Cooperation (APEC) Mutual Recognition Arrangement for Conformity Assessment of Telecommunications Equipment, Phase 1 - Bilateral Implementing Agreement between the United States of America and Chinese Taipei

Telecommunication Equipment Requirements

Under the Taiwan Telecommunications Act, telecommunications equipment approval is the responsibility of the Directorate General for Telecommunications (DGT). Under the terms of Phase I procedures of the APEC MRA, DGT has agreed to accept test reports issued by CABs designated by NIST to be used in the equipment approval process.

Article 42 of the Telecommunications Act stipulates that three basic principles must be satisfied concerning technical standards and requirements for telecommunications terminal equipment:

1. The connection shall cause neither damage to the telecommunications machinery and line facilities of a Type I telecommunications enterprise nor faults in the performance of such facilities.
2. Other users of the telecommunications machinery and line facilities of a Type I telecommunications enterprise shall not be injured.
3. A clear division of duties in regards to the telecommunications machinery and line facilities of a Type I telecommunications enterprise and the terminal equipment connected by users shall be ensured.

Laboratory Criteria for Designation by NIST

In order for a U.S. laboratory to be designated as a CAB to test covered telecommunications equipment and issue test reports acceptable to the DGT, the laboratory shall satisfy the following criteria:

1. The laboratory shall be accredited to conduct applicable test methods of its choice according to its particular interest and demonstrated competence.
2. An accredited laboratory must be familiar with the DGT requirements applicable to their scope of activity. The DGT requirements for all covered products can be found at their website http://www.dgt.gov.tw.

Some of the DGT technical regulations have specified test methods that must be used, others do not have such specification. The laboratory may select which test method(s) that it will use according to the following:

A. When specified - the specified Chinese National Standard (CNS)

B. When not specified - any test method that it is accredited to perform which will satisfy the specific DGT requirement:

   1. Chinese National Standard (CNS)
   2. International Telecommunications Union (ITU) standard
   3. Other international standard, e.g. ISO/IEC
   4. Local standard

Note: Additional requirements for EMC are contained in a separate supplement available on request from NIST

4. Inter-American (CITEL) Mutual Recognition Agreement for Assessment of Telecommunications Equipment, Phase I

The CITEL MRA has not progressed far enough to begin the Conformity Assessment Body (CAB) designation process, but it will require accredited test laboratories under Phase I procedures. Participating CITEL economies will most likely be at least Argentina, Brazil, Chile, Mexico, and the United States.

U.S. CAB Requirements

A U.S. CAB must be accredited to ISO/IEC International Standard 17025: *General Requirements for the Competence of Testing and Calibration Laboratories,* or in the short term prior to complete implementation of ISO/IEC International Standard 17025, to ISO/IEC Guide 25: *General Requirements for the Competence of Calibration and Testing Laboratories* to perform the required testing, by a NIST-recognized accreditor that complies to ISO/IEC Guide 58. In addition to being capable of performing specific test methods, a CAB must understand each individual partner's regulations and the approval process for the equipment that they desire to be designated to test.

APPENDIX B

GENERIC REQUIREMENTS, PROCEDURES, AND CONDITIONS FOR ACCREDITATION BODY RECOGNITION

1.0 INTRODUCTION

This document specifies the generic requirements, procedures, and conditions for accreditation body recognition. This document was developed with reference to existing international guides and standards and is not intended to supercede or contradict the principles represented in those documents.

2.0 ACCREDITOR REQUIREMENTS

The basic generic criteria that an accreditor must satisfy are contained in ISO/IEC Guide *58: Calibration and Testing Laboratory Accreditation Systems - General requirements for Operation and Recognition.* An accreditor shall accredit laboratories against ISO/IEC International Standard 17025: *General Requirements for the Competence of Testing and Calibration Laboratories*, or in the short term prior to complete implementation of ISO/IEC International Standard 17025, against ISO/IEC Guide 25: *General Requirements for the Competence of Calibration and Testing Laboratories.* Other additional requirements or specifications mandated by law or contract shall also be taken into account where applicable.

3.0 ACCREDITATION BODY EVALUATION PROCESS

The process of evaluating an accreditation body for recognition consists of a number of activities, which must take place prior to and after granting recognition. The process consists in general of a review of the accreditation body's quality system, on-site evaluation/re-evaluation of the premises, witness audits of assessments performed by the accreditation body's assessors, writing an evaluation report, review of accreditation body response to the evaluation report, and final evaluation and decision. Surveillance activities and on-site reevaluation visits of recognized accreditors are conducted periodically.

3.1. Quality System Review and Evaluation

An accreditation body seeking recognition must submit copies of its quality documentation for review and evaluation. The documentation must show that the quality system promotes an adequate level of performance and quality management. If the accreditation body cannot submit documentation in advance, the quality system review and evaluation can be performed during the on-site evaluation.

3.2. On-site Evaluation

An on-site evaluation of an accreditation body's facilities is conducted prior to initial recognition and at regular intervals thereafter, as specified by relevant national or international practice, unless the recognition is terminated. The evaluation encompasses an on-site review of selected procedures and operations for all sites involved in the accreditation activities that the recognition would cover. An accreditation body may appeal the inclusion of any member of

the evaluation team proposed for the on-site evaluation. Such appeal must be received in writing no later than 20 working days after notification of the accreditation body of the membership of the evaluation team and must provide a substantive reason for a change to be made.

3.3. Witness Audits/Assessments

As part of the evaluation process, an accreditation body must allow members of the evaluation team to witness the accreditation body's auditors/assessors performing an assessment/audit of a client's facilities. The number and identity of the witness audits to be performed will be determined in consultation with the accreditation body. As a general practice, at least two witness audits will be performed.

3.4. Final Report

The evaluation team prepares a final report after the evaluation and forwards it to the accreditation body. The final report usually will be essentially the same as the draft report unless additional information has been uncovered or issues that require clarification have arisen.

The final report normally presents the definitive findings of the evaluation. However, if additional information surfaces with significant bearing on the evaluation, a supplementary report may be necessary. Any supplementary report that requires action will be promptly forwarded to the accreditation body.

3.5. Accreditation Body Response to Evaluation Report/Deficiency Notification

The accreditation body must respond in writing to all identified deficiencies. All specific corrective actions taken, and proposed plans to resolve each deficiency, must be described in writing. Plans must include specific actions, time frames, dates, etc. In some cases, an additional on-site visit may be necessary to observe stated resolutions.

Accreditation bodies holding a current valid recognition must respond to any deficiencies identified within 30 days of receipt of a notification and have an approved plan to implement the corrective actions within 90 days of receipt or recognition may be suspended until full conformance is demonstrated.

3.6. Final Evaluation Decision

Upon completion of all evaluation activities, an evaluation panel will be convened to review all information collected regarding an accreditation body and make a final decision on the appropriate recognition action to take. The decision is based on the review and evaluation of all materials submitted by the accreditation body, reports covering the quality system review, on-site evaluation(s) report, witness audit reports, and deficiency resolution information.

3.7. Surveillance

A full or partial on-site visit or other forms of surveillance of a recognized accreditor or any accredited body may be conducted to observe or verify conformance with program requirements. Any deficiencies noted as a result of surveillance must be responded to in accordance with Paragraph 3.5 above.

4.0 PROGRAM ACTIONS

A program for recognition of accreditation bodies shall have in place procedures for granting, denying, suspending or terminating recognition of an accreditor. Accreditors subject to an adverse action shall be provided with at least the following options: appeal of the decision, submission of additional information for further evaluation, or acceptance of the decision. The appeals process shall be clearly defined and may include the use of Alternative Dispute Resolution as appropriate.

5.0 OBLIGATIONS OF A RECOGNIZED ACCREDITOR

5.1. Continuous Conformance

It shall be incumbent upon a recognized accreditor to conform to all requirements throughout the period of participation. Failure to maintain conformance is cause for suspension or termination of recognition.

5.2. Proper Use of Recognized Status and Claims

A recognized accreditor shall not make any claim which:

a) constitutes or implies certification, approval, or endorsement of any product manufactured or entered into commerce in the United States based on its recognition;

b) constitutes or implies that the accreditor or an accredited body is recognized for any activities other than those specifically stated in the recognition documents.

A recognized acereditor must follow documented guidance when advertising its recognition status on letterheads and in brochures, reports, and professional, technical, trade, and other publications.

APPENDIX C

NIST VERIFICATION PROCESS

This Appendix outlines the NIST process, referenced in Article 3.1 of the NIST-NACLA Memorandum of Understanding (MOU), for verifying that (1) NACLA recognition of laboratory accreditation bodies is carried out in conformance with the technical criteria found in Appendix B of the MOU, and (2) NACLA recognition fulfills the requirements of the international agreements and arrangements set forth in Article 2.3, Article 2.4, and Appendix A of the MOU.

The NIST verification process will include the following elements:

1. NIST will compare the NACLA Recognition Procedures with Appendix B of the MOU to determine that Appendix B criteria have been adequately addressed.

    a. NIST will ensure that accreditation bodies and laboratories have copies and understand the technical requirements set forth in intergovernmental agreements (Appendix A) or U.S. government agency specifications. NIST will work with other Federal agencies to define these specifications when requested to do so by NACLA.

2. NIST will review NACLA's plan to build on the existing general NACLA recognition program to take into account the supplemental technical criteria listed in Appendix A of the MOU or contained in U.S. government agency specifications.

3. A NIST representative will participate as an observer or as an evaluation-team member for all initial evaluations of laboratory accreditation bodies seeking recognition for any activity or activities covered under the provisions of the NIST- NACLA MOU.

4. A NIST representative will participate on NACLA acceptance panels considering laboratory accreditation bodies for recognition for any activity or activities covered under the provisions of the NIST-NACLA MOU.

It is understood that initial implementation of the NIST-NACLA MOU will necessitate putting in place an interim process for those laboratory accreditation bodies that have completed the NACLA evaluation process prior to the MOU being put in place, and that are either candidates for NACLA recognition or have already obtained NACLA recognition. In these cases, NIST representatives will review the NACLA evaluation team reports on accreditation body evaluations to verify that written criteria have been addressed by evaluation teams and to confirm that identified nonconformances have been addressed by the accreditation body being evaluated. If necessary, in advance of the completion of the NACLA plan referenced in Item 2 above, NIST and NACLA will jointly develop an interim witness audit plan to evaluate conformance to supplemental technical requirements outlined in Appendix A of the MOU or contained in U.S. government agency specifications.